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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,559	08/20/2001	Veerappa S. Subramanian	4961-5	6556

7590 05/20/2003

Kent H. Cheng, Esq.
Cohen, Pontani, Lieberman & Pavane
Suite1210
551 Fifth Avenue
New York, NY 10176

EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,559	SUBRAMANIAN ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response filed 2/12/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the claims to exclude acidic pharmaceutical carriers as stabilizing agents, yet there are no enabling disclosures in the originally filed specification that would exclude such stabilizers. The current specification as filed is silent to the expressed exclusion of acidic pharmaceutical carriers as stabilizers. The specification also lacks disclosures to how 'substantially free' the composition would have to be in order to be commensurate with the scope and spirit of the instant invention. Since the specification is not enabled for such disclosures, a skilled artisan would be unable to practice the invention.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowey (USPN 4,680,323) in view of Baker et al (USPN 4,687,660) and Seth (USPN 6,033,686). The claims are again drawn to a solid dosage form of bupropion HCl. The dosage form is a sustained release tablet and the composition comprises carboxyvinyl polymer and microcrystalline cellulose or lactose. In addition the stabilization profile discussed above, after 2 weeks of storage at 55 degrees Celsius, there is at least 90% w/w of the bupropion remaining in the composition. The carboxyvinyl polymer provides a release profile where the drug is released from a period of 8 to 24 hours. Applicant recites a specific profile where the drug is release in a particular percentage at a particular time (i.e. 30 – 45% within 1 hour, 60 – 80% in 4 hours, etc.). Claim 9 recites a method of stabilizing the drug comprising combining the constituents, and granulating with purified water.

Lowey discloses a pharmaceutical tablet comprising pharmaceutically active agents, carboxyvinyl polymer and other cellulose derivates as excipients. Various classes of pharmaceutical agents are useful in the formulation including analgesics and bronchodilators (Abstract). The carboxyvinyl polymer allows for the active agents to be released over a 24-hour period (col. 3, lin. 55-60). The carboxyvinyl polymer is present in a concentration of from 1-90% (claims). What is lacking in the reference is a disclosure of the particular active agent, bupropion hydrochloride, and the other excipients recited by the claims, microcrystalline cellulose and/lactose.

Baker et al discloses a bupropion hydrochloride composition comprising water-soluble and insoluble polymers such as cellulose derivatives. The composition further comprises lactose (examples).

Seth however discloses a sustained release tablet comprising bupropion HCl, a water insoluble, water-permeable film-forming polymer and water-soluble polymer. The tablet releases 30 – 60% of the bupropion HCl after 1 hour, 55 – 80% after 2 hours, 75 – 95% after 3 hours, and 80 – 100% after 4 hours (col. 3, lin. 40 – 56). Seth also discloses a method of preparing the composition comprising mixing the constituents and granulating with purified water (examples). Though the reference does not explicitly claim this process as stabilizing, Seth's final product is a stable tablet.

With these aspects in mind it would have been obvious to one of ordinary skill in the art to combine the teachings and suggestion of the art. A skilled artisan would have been motivated to combine the teachings of Lowey with Baker since they share similar active agents namely psuedephedrine HCL. A skilled artisan would have been able to substitute the bupropion HCL of Baker into the formulation of Lowey, along with the lactose of the formulation in order the effect the release of the drug. Release profiles can be manipulated through concentrations of the non-active excipients, and is within the level of skill in the art. A skilled artisan would have further been motivated to combine the purified water and further excipients of Seth in order to better refine the processing and release profile of the active agent. Seth releases bupropion HCL with ethyl cellulose as a possible excipient, similar to Baker. A skilled artisan would have been motivated to make these combinations and substitutions in order to optimize the release of a bupropion HCL tablet. An expected result of such a combination would have been a tablet with a release profile and consistency useful as an anti-depressant.

Response to Arguments

4. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
May 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600